

# Quality Control Perspectives during Mass Production with a Focus on the Chemical Industry

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## Abstract

Mass production was part of the industrial revolution in 1870 and, with it, a huge step change in manufacturing processes. Its impact was ground breaking and became even more remarkable with automation in a business production environment. The chemical industry is one of the manufacturing sectors that has benefited from the technology of mass production achieved through automating the business process. In this era of industry 4.0 and with the associated advanced technologies of smart manufacturing, cloud computing, cyber physical systems and internet of things, mass production has been revolutionised but still faced issues such as quality control of the production process which was affected by supply chain management, customised production of commodity and specialty chemicals and huge demand from other chemical industry manufacturers. This chapter has reviewed the evolution of mass production during traditional manufacturing to the present day and carried out a risk assessment to quality of production in a mass production environment with a view to recommending adequate quality control of the production process. The chapter also included a case study for mass production of a pharmaceutical drug—Amoxicillin which was partly batch produced into dry powder and then mass produced using tableting and encapsulating machine, highlighting sources of contamination and inconsistency in tablet weight if adequate control measures were not put in place.

**Keywords:** mass production, quality control, chemical industry, risk assessment, manufacturing, tableting/encapsulating

## 1. Introduction

Manufacturing is essential to a nation's economic well-being and quality of life for citizens because it creates wealth which is distributed through high-value jobs. Since its birth two centuries ago, the manufacturing industry has evolved through several paradigms [1]. The first paradigm was craft production which created the product requested by the customer at a relatively high cost. The reason is that there were no manufacturing systems associated with this paradigm. Also, craft production was confined to localised geographical regions and such production process was not scalable or interchangeable. Subsequently, the moving assembly lines then enabled the development of mass production which provided low-cost products through large scale manufacturing. However such production was limited in variety, as evidenced by the famous statement about colour that he wanted so long as it was black.

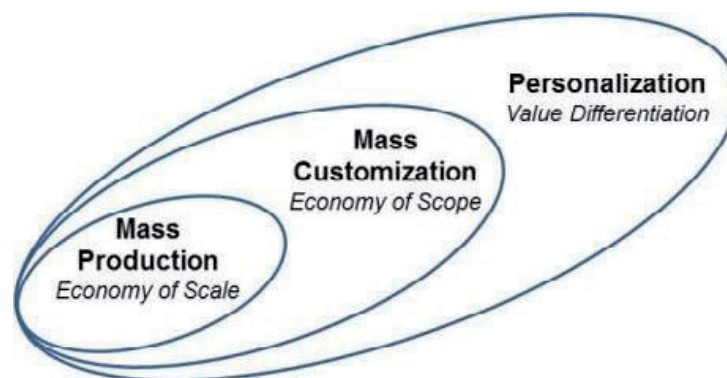
Mass production evolved as a method of producing goods in large quantities at a low cost per unit. It was kicked off with a moving assembly line at Highland Park near Detroit, Michigan named after Henry Ford. Mass production was fully established and massively utilised at the end of the World War II when demand for consumer products became very high [1]. This technology was sought after because of the concepts of parts interchangeability, moving assembly lines and scientific management which are key enablers for mass production. While mass production created tremendous wealth for the U.S. and many individuals, it also had several weaknesses. Although massively revolutionised, it still faced issues such as quality control of the production process attributed to supply chain management, customised production of commodity speciality chemicals and huge demand from other chemical industry manufacturers. This book chapter therefore will review the evolution of mass production during traditional manufacturing to the present day and then carry out a risk assessment of quality of production in a typical chemical industry mass production environment with a view to managing and recommending adequate quality control of the mass production process.

In the late 1980s, global competition and consumer demand for high product variety led to the development of mass customisation. This was achieved by manufacturers designing the basic product architecture and possible options while customers selected the assembly combination of their choice. Product family planning then enabled manufacturers to share certain common components for a range of family of products.

**Figure 1** shows how mass production with a key objective of economy of scale can be differentiated from mass customisation involving mass production of specific products for a large variety of customers while exploiting the economy of scope. Another option is personalisation which designs/produces products which are personalised for individuals thereby achieving a high level of value differentiation for specific users.

**Figure 2** shows that the goal of mass production is scale while for mass customisation it is both scale and scope of production. For personalised production the goal is scale, scope and value derived. Overall, the desired product characteristics is quality and cost during mass production, quality, cost and variety for mass customisation and quality, cost, variety and efficacy for personalised production. It is therefore assumed that during mass production the customer buys the product while during mass customisation the customer chooses what they wish to buy. A request for personalised production requires the customer to design, choose and then buy the product.

During mass production, mass customisation and personalised production the emphasis and key objective is to produce very large quantities of the product within



**Figure 1.**  
*Goals of the manufacturing paradigms [1].*

	Mass Production	Mass Customization	Personalized Production
Production Goal	Scale	Scale Scope	Scale Scope Value
Desired Product Characteristics	Quality Cost	Quality Cost Variety	Quality Cost Variety Efficacy
Customer Role	Buy	Choose Buy	Design Choose Buy
Production System	Dedicated Mfg Systems (DMS)	Reconfigurable Mfg Systems (RMS)	On-Demand Mfg Systems (OMS)

**Figure 2.**  
*Differences between mass production, mass customization and personalised [1].*

a limited time scale to satisfy customer demand. Monitoring manufacturing quality therefore could prove difficult considering that satisfactory product quality can only be achieved by rapid screening of materials at the input stage, transformation process stage within the manufacturing hub and finally at the output stage before shipment to the customer. The aim of this chapter therefore, is to review a typical mass production process, understand current practice to guaranteeing quality assurance during mass production and finally propose how this can be implemented in the chemical industry. It will also develop risk assessment that could guide process quality monitoring during mass production.

**2. Background and literature review**

There are four industrial revolutions so far [2] including first industrial revolution associated with discovery of water and steam power engine in 1784, the second industrial revolution in 1870 which involved *mass production* using electrical energy, the third industrial revolution in 1970 which introduced the use of information technology systems for automation and the fourth industrial revolution describing the present day which embraces Internet of Things (IOT) and cyber physical systems (CPS). The industrial revolutions which commenced over three centuries ago therefore have evolved and formed the backbone of manufacturing with each revolution providing a boost to productivity in the sector. Since the second industrial revolution mass production has sustained high volume production to satisfy global demand and needs. The manufacture of cars, guns and fast food are examples of mass production. It is the machine tool industry that gave rise to the idea of mass production because it motivated innovators in Britain and the United States to commence production of interchangeable parts.

Henry Ford was known to have invented an improved version of the assembly line for mass production when he mass produced the Curved Dash Oldsmobile. Ransom Eli Olds in 1901 in the USA. On this occasion he was said to have conceived the basic concept of the assembly line out of which 425 Curved Dash Oldsmobiles

were manufactured. This significant development led the automotive manufacturing market over a period of 3 years from 1901 to 1904 [2]. It was also noteworthy that Henry Ford improved his design and installed the first conveyor belt assembly line around 1913 which reduced the building time of the Model T version to just 93 minutes. During that period, Ford became the world's-largest car manufacturer, having produced more than 15 million Model Ts by 1927 using the enhanced assembly line concept.

Other sectors have benefitted immensely from mass production such as the fast food and electronics industries to name a few. In the food industry, for instance, beverages, canned and bottled soft and alcoholic drinks and dried food packs are mass produced daily to satisfy huge global demand.

The advantages of mass production are [2]:

- a. It is usually 'automated' to the highest extent possible.
- b. Labour costs are reduced substantially.
- c. It engenders a faster rate of production.
- d. Although capital and energy investment are increased total expenditure per unit of product is decreased.
- e. Rate of production is enhanced.

The disadvantages of mass production are:

- a. Mass production infrastructure is very expensive to set up.
- b. The workers are not highly motivated, since their work is very repetitive.
- c. Manufacturing system is not very flexible, and production line is difficult to adapt.
- d. If one part of the line breaks, the whole production process will halt until it is repaired.

## 2.1 Quality management during mass production

During mass production, mass customisation and personalised production the emphasis and key objective is to produce very large quantities of the product within a limited time scale to satisfy demand. Monitoring the entire manufacturing process in terms of quality therefore could prove difficult considering that satisfactory manufacturing quality can only be achieved by rapid screening of materials at the input stage, transformation process stage within the manufacturing hub and finally at the output stage before shipment to the customer.

Recalls from mass production such as for cars, processed food and aircrafts have frequently been reported, even for the case where the rate of defects is only of the order of ppm or less. Even if the defect rate is of the order of ppm or less, most of the remaining safe products would also need to be recalled and may be destroyed or replaced by new ones. Such recalls are always cost intensive. During mass production it is very difficult using conventional quality control methods to find defects of the order of ppm or less at the stage of design and production.



Murakami [3] researched on a solution that could obviate the recall problem of the order of ppm during mass production. His new quality control method detects defects of the order of ppm or less for mass production products. This was based on the statistics of extremes successfully applied to the fatigue strength evaluation of defective materials. He confirmed that the same method could be applied, not only to mass production, but also for large machine components produced in large numbers.

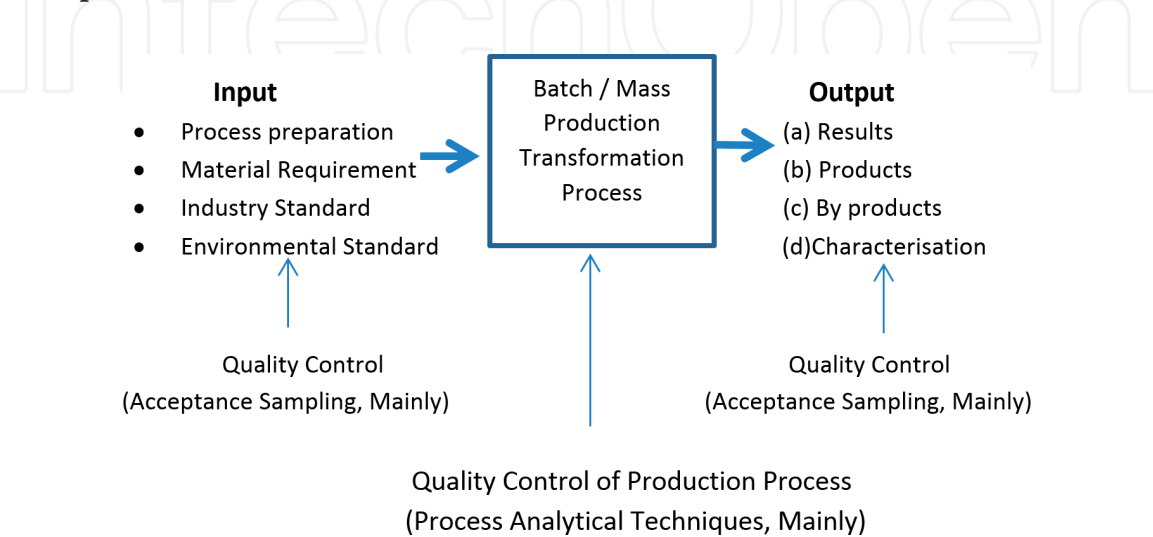
**Figure 3** shows hypothetical model of an input, manufacturing transformation and output for a production process. Input to the process could be in form of raw materials, catalysts and information; the transformation process involves a transition stage where the input materials are combining under the relevant conditions, such as temperature, pressure, etc. to produce the target output. The model shows that for each of the three stages there would need to be control in place to achieve the target/desired quality. In a mass production/continuous processing environment it may not be feasible to evaluate every single item going through the process and also at the output. Rather, acceptance sampling is used for quality assurance.

Siddiqui et al. [4] have reviewed the applications of analytical techniques including acceptance sampling in pharmaceutical analysis of drugs. They confirmed that pharmaceuticals may develop impurities at various stages of their development, transportation and storage, Consequently they need to be characterised and components quantified.

**Table 1** shows common analytical techniques for quality control during mass production of chemicals. During chemical manufacture process analytical techniques are used to measure bulk materials, intermediates, impurities and degradation products. The aim is to characterise the quality of materials by setting limits of their active ingredient content [4].

The common analytical methods presented in **Table 1** include titrimetry, chromatography, spectroscopy, electrophoresis, electrochemical methods and electrophoresis.

Acceptance sampling as a statistical method is also used to inspect bulk materials and mass-produced products to determine if they meet the required specifications. Acceptance sampling plan guarantees that the average quality level or percent defectives actually produced for consumers will not exceed a specified limit. It is therefore an effective way to ensure the high quality of mass-produced products and is usually conducted on the basis of a reference standard, or system of inspection rules [4].



**Figure 3.**  
*Model for quality control during mass production.*

Process analytical technique (PAT)	Variants of the technique
(1) Chromatography	a. High performance thin layer chromatography b. Thin layer chromatography c. High performance liquid chromatography d. Gas chromatography
(2) Spectroscopy	a. Nuclear magnetic resonance spectroscopy b. Infra-red spectroscopy c. Near infra-red spectroscopy d. Spectrophotometry e. Flourimetry f. Phosphorimetry
(3) Electrochemical method	a. Voltammetry b. Polarography c. Amperometry d. Potentiometry
(4) Flow injection and sequential injection analysis	
(5) Electrophoresis	
(6) Titrimetry	

**Table 1.**  
*Common analytical techniques used for quality control during batch and mass production.*

Quality analysis by acceptance sampling is measured by the following variables [5]:

- a. Acceptable quality level (AQL): this is the desired quality level at which the probability of acceptance is high. It is described as the maximum proportion of defectives which the consumer finds acceptable. it is therefore the maximum percent defectives that can be considered satisfactory during sampling.
- b. Lot tolerance percent defective (LTPD) or reject able quality level (RQL): this is the quality level at which the probability of acceptance is low and below this level the batch is rejected. This could be described as the dividing line between good and bad lots. Lots at this quality level however, are considered to be poor and are classed as average outgoing quality (A.O.Q)

Advantages of acceptance sampling:

- i. It is applicable to industries where there is mass production which follows a set production procedure.
- ii. The method is economical and easy to understand.
- iii. Products that are delicate to handling during inspection can be inspected by sampling.
- iv. Acceptance sampling enhances scheduling and delivery times.

Limitations of acceptance sampling:

- i. Sampling does not guarantee 100% batch quality and there is risk of sub-standard output.

ii. Success of the system is dependent on, sampling randomness, quality characteristics to be tested, batch size and criteria of acceptance of lot.

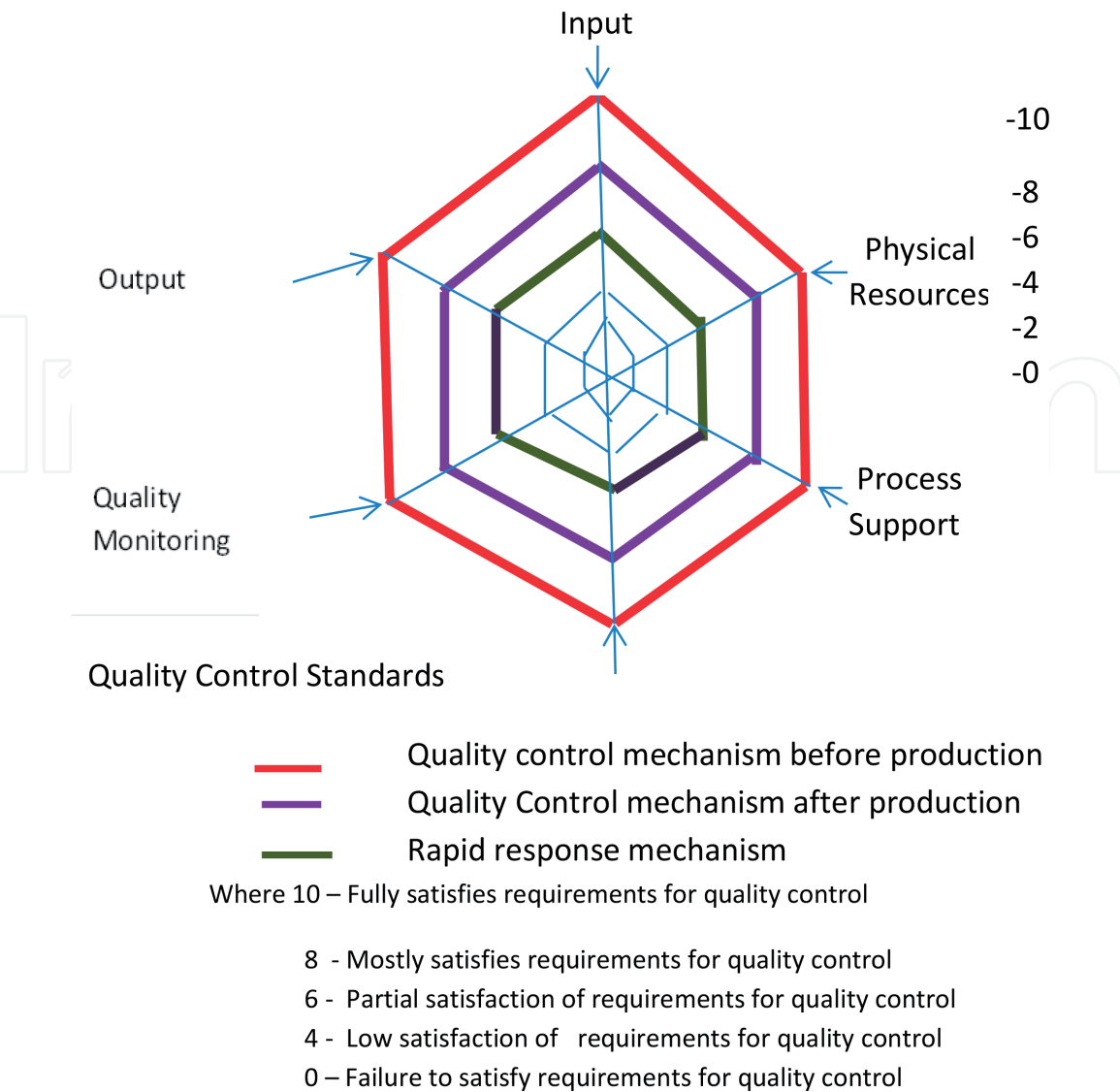
- Producer's and consumer's risk: the acceptance or rejection of the whole batch of products in acceptance sampling depends upon the results of the sample inspected. There is always a chance that a sample may not be true representative of the batches or lots from which it is drawn. Consequently, there are two types of risk;
- Producer risk ( $\alpha$ ): probability of a batch being good overall or even better than acceptable quality level (AQL) but due to bad sampling it is rejected. So this probability of rejection of a good lot which otherwise would have been accepted is known as producer's risk ( $\alpha$ ).
- Consumer risk ( $\beta$ ): probability of a bad batch or substandard quality being accepted however produces a good sample and consequently accepted. So this probability of a defective lot being accepted which otherwise would have been rejected is known as consumer risk ( $\beta$ ).

Guoa et al. [6] designed a quality control mechanism by scoring the quality of input, the transformation process and the output score. In their study they developed a six component process analysis turtle diagram quality scoring system. The assessment system is based on input material resources, the process support, quality control standard, quality manufacturing control method and the output, forming a quality control mechanism analysis model presented as a radar map.

**Figure 4** adapted from [6] shows the radar model for quality control mechanism during manufacture. It shows the six variables that would need to be monitored during a production process as input, output, quality monitoring, quality control standards, process support and physical resources. It also shows the levels of expectation for the variables measured quantitatively.

Switching from batch to continuous pharmaceutical mass production offers several advantages, such as increased productivity, steady product quality and decreased costs. Kirchengast et al. [7] presented a control strategy for direct compaction on a continuous tablet production line consisting of two feeders, one blender and a tablet press (TP). They also applied a data-driven, linear modelling approach to develop a Smith predictor for active pharmaceutical ingredient concentration control and a model predictive controller responsible for the TP hopper level. In case of severe concentration variations the system could discard out-of-specification material before it entered the TP. The authors tested effectiveness of the control concept in a simulation as well as by implementing it on a real pilot plant.

Mass manufacture of micro products in the present day is quite challenging since tools, materials and technologies have to be scaled down from the macro to the micro domain. This is mainly because downscaling of the basic classical process would lead to unexpected process behaviour which poses new challenges for in-process quality inspection desiring a reliable quality control. To implement this in a mass production environment therefore, new strategies to plan the process while focussing on the logistics of the quality parameters would become essential. Weimer [8] introduced a closed-loop quality control strategy for bulk production in micro cold forming. A discrete event simulation model incorporating characteristics of optical quality inspection and general process parameters allows the quantification of the system's performance.



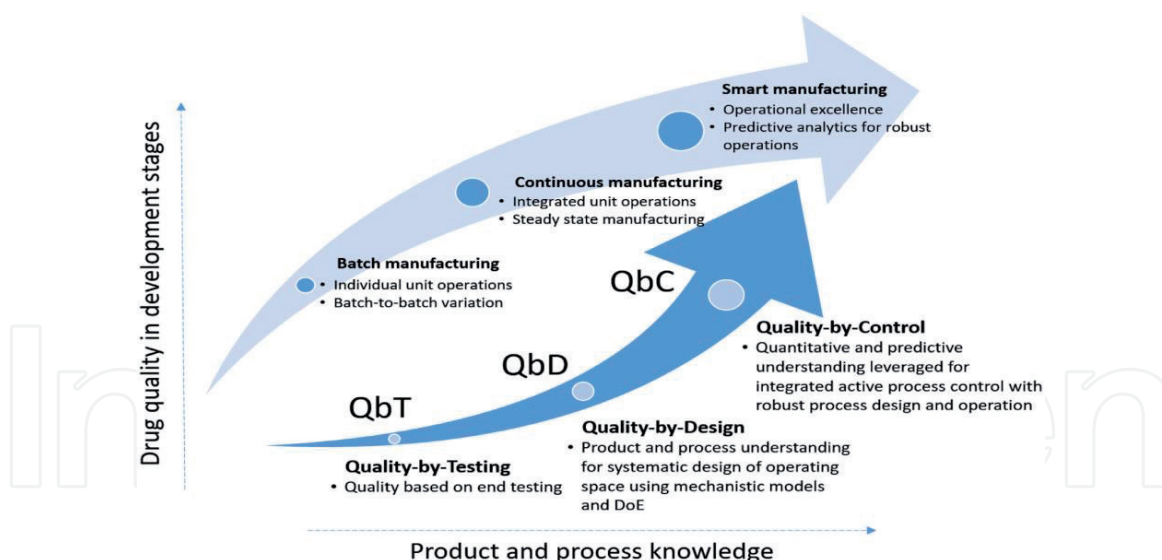
**Figure 4.**  
*Model for quality control mechanism.*

### 2.1.1 Quality control strategies for mass production

A three-level quality control strategy for a continuous manufacturing process was proposed to maintain the quality of the product in response to potential variations or disturbance in the process, equipment conditions, incoming raw materials, or environmental factors over time Yu et al. [9]. A Level-3 quality control strategy imposes strict constraints on attributes and parameters that could affect product quality while also relying on rigorous end-product testing that should guarantee final product quality. Tight quality control of this nature is also used in a batch manufacturing environment and quality by testing (QbT) situation. This is managed by tracking a manufacturing operation to ensure that relevant parameters are maintained within the desired constraint. It is also necessary at the early stage of drug development to have a clear understanding of how raw material and process variability could affect product quality to fully appreciate the level of quality control. There is a perceived view that this approach is not feasible to be effectively implemented in continuous manufacturing processes.

The US Food and Drug Administration (FDA) recognised that increased testing does not necessarily improve product quality and thus quality must be built into the product [10], following the QbD concept. Consequently, pharmaceutical quality by





**Figure 5.**  
 The systematic progression in quality assurance via QbT, QbD and QbC [10].

design (QbD) has now evolved guided by standardised documents associated with Pharmaceutical Development, Quality Risk Management, Pharmaceutical Quality System and Development and Manufacture of Drug Substances [10].

Quality by design (QbD) finally matured and evolved into quality by control (QbC) which describes the design and operation of a robust manufacturing system. This is normally achieved by an integrated and comprehensive process control underpinned by automation principles and also based on a clear understanding of the process. Overall therefore, Quality by Control enables a continuous monitoring and control of process operations and systematic release of the correct specification of manufactured products in real time.

**Figure 5** shows a plot of drug quality in development stages vs. Product and Process knowledge. It demonstrates the evolutionary process of batch manufacturing through to continuous manufacturing and then smart manufacturing and the corresponding quality assurance checks in place. As drug quality development progresses from the batch to continuous and then smart manufacturing, quality assurance changes from quality by testing to quality by design and then consolidating to quality by control based on standards and requirements.

### 2.1.2 Quality control during bulk pharmaceutical production

In continuous chemical production lines, materials are transformed into final products and by-products and sometimes the activities take place in different departments. Overall, the quality of the final products is dependent on the quality of the input materials, the state of the relevant manufacturing equipment and the performance of the operators. However, out of control situations along production lines would normally lead to loss in operation time, material and financial resources. Sahebjamnia et al. [11] proposed a Fuzzy Q-learning Multi-Agent Quality Control System (FQL-MAQCS) to control a continuous chemical production line. The system manages unforeseen circumstances during production through a multi-agent based system. It consists of quality control executor, process data analyst, central decision-maker, departmental decision-maker and knowledge/rule manager agents. The system is also self-learning, updated periodically and information gathered could be stored in a knowledge base. FQL-MAQCS has been tested in a real case study situation and the results demonstrate the usefulness, robustness and capability of the developed quality control system.

Pharmaceutical production is now progressing more into mass personalization, down to lot size  $N = 1$ . Each product is not only produced as part of a batch during mass production but it is also designed uniquely for the benefit of a specific patient. Based on demand certain drugs are custom designed and manufactured for large hospital or community pharmacies. An ongoing trend is an increased usage of contract manufacturing/filling by most pharmaceutical companies. Highly flexible aseptic production and filling lines have now become trendy until recently was not feasible through filling line concepts available in the present day but only through highly flexible automated systems driven by robotics [12]. The popular technology of individualised/customised mass production of cars in terms of colour, engine specification and performance, wheels, lighting and extras is still remote in current pharmaceutical production technologies. If successfully implemented, this would be a revolution in pharmaceutical manufacturing and also for the Food and Drug Administration (FDA). Bhaskar [13] designed an advanced model predictive control (MPC) architecture integrated with a novel real-time tablet weight measurement method aimed to develop and implement continuous direct compacting tablet manufacturing pilot-plant which has the potential to control tablet weight and tablet breaking force simultaneously by systematically decoupling and cascading the control loops. The predictive control algorithm (PCA) was superior to the proportional, integral and derivative (PID) controller and consequently could be utilised for a wide range of applications to improve the quality of pharmaceutical products during continuous manufacturing. The MPC enabled control of the main compression force and pre compression force using main compression height and fill depth respectively as the actuators. The researchers claimed that developing this technology made it possible to measure tablet weight and other variables that enhanced manufacturability of pharmaceutical tablets.

Lakerveld et al. [14] in a separate study designed a plant-wide control structure for a continuous pharmaceutical pilot plant used to classify control objectives. By means of simulation software they demonstrated that for selected parameters the critical quality attributes (CQAs) of the final product can be kept close to specification in the presence of significant and persistent disturbances. This shows flexibility to control CQAs independently of each other.

Mesbah et al. [15] developed a control strategy based on a non-linear moment model whose optimal operation was based on manipulation of heat input to a crystallizer such that a maximal allowable crystal growth rate was maintained during a production process. The feedback structure of the control framework enabled the optimizer to reject process uncertainties and accurately account for plant-model mismatch while fulfilling product quality requirements.

Advanced feedback control concepts which are capable of improving performance of batch processes, as well as enable technologies from batch to continuous manufacturing were developed by Nagy et al. [16]. These were used in the improvement of pharmaceutical particulates, especially in the application to continuous drug substance/product manufacturing. Mathematical modelling of the optimal design, start-up and control of anti-fouling and continuous crystallisation processes to achieve and maintain the desired controlled stage of operation was demonstrated. Su et al. [17] demonstrated the use of a rotary tablet press, integrated into a pilot scale continuous direct compaction process. The outcome was that active process control which was based on product and process knowledge and advanced model-based techniques, data reconciliation, model predictive control and risk analysis, appeared to be indispensable when implementing a comprehensive Quality by Control. It also appeared to guarantee robustness and production efficiency. Recently, Singh [18] developed an automated version of the continuous pharmaceutical manufacturing pilot plant. The feeder, comill, blender and tablet

press unit operations of the pilot plant were integrated with a centralised control platform enabling the whole plant to be operated automatically. Data generated from all the unit operations were capable of being collected and stored systematically in a data base.

#### 2.1.2.1 Contamination quality control during manufacturing

Contamination quality control is a huge challenge during manufacturing especially for products with ultra-low tolerance for impurities and contaminants. For instance during the manufacture of premium chemicals, highly sterile pharmaceuticals and hygienic products and other products with high purity requirements and specifications, it is essential to provide an environment that will obviate any form of contamination. A common source of contamination is from manufacturing machines and equipment that can conceal microscopic particles and microbes. Decontamination can be achieved through effective cleaning and disinfecting manufacturing equipment at regular intervals and ensuring that all surfaces exposed to raw materials and products can be reached by the cleaning and disinfection processes. Hydrogen peroxide is widely recommended for the cleaning and fumigation process and therefore all machine housing and operating components and interfaces need to be robustly designed to minimise any form of contamination from these. Manufacturing equipment therefore should be designed to be resistant to chemicals, display low adsorption affinity for hydrogen peroxide during fumigation and also its rapid desorption during aeration in order to speed up the production process [12].

Kraemer et al. [19] researched on clean ability test of a robot contamination with a water-based fluorescing test contamination. The researchers mixed riboflavin in ultra-pure water which was then allowed to dry onto the manufacturing surfaces. On inspection under UV light before and after manual wipe cleaning with a pre wetted polyester knitting cleanroom wipe using ultrapure water, they observed areas that were difficult to clean because of the use of the fluorescing pigment riboflavin. This included depressions, indentations and edges.

### 3. Case study: process flow diagram for the manufacturing process of amoxicillin

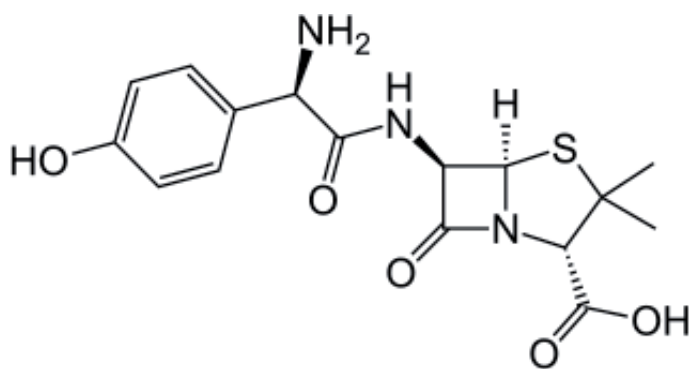
Amoxicillin oral suspension is an antibiotic which most commonly utilised for first line treatment of middle ear infections and for pneumonia, skin infections and strep throat as well. Active compound used in its formulation has chemical formula  $C_{16}H_{19}N_3O_5S$  with molar mass of 365.4. It is also called phenoxymethyl penicillin. **Figure 6** shows a variety of Amoxicillin capsules and tablets while **Figure 7** shows the structural formula of Amoxicillin. **Figure 8** is GSK Manufacturing Plant at Irvine.

**Figure 9** shows the process flow diagram for manufacture of Amoxicillin [20]. The process starts from stage A involving the reaction of the relevant raw materials [6-aminopenicillanic acid (6 APA), water and hydroxy phenyl glycine methyl ester (HPGME) and phenyl glycine acylase (PGA)] necessary for manufacture and finishes at stage O which is the drying process. Quality control of the manufacturing process takes place at every stage to ensure that the finished product in a dried form has the target consistency of 100% amoxicillin with minimum impurity. Most of the unit operations up till this stage are mainly batch manufacturing processes. The dried amoxicillin powder would need to be quality tested by acceptance sampling using relevant analytical techniques to establish conversion consistency and consequently any impurities beyond the recommended concentration in parts per million (ppm).





**Figure 6.**  
*Amoxicillin capsules and tablets.*



**Figure 7.**  
*Structural formula of amoxicillin (6-aminopenicillanic acid).*

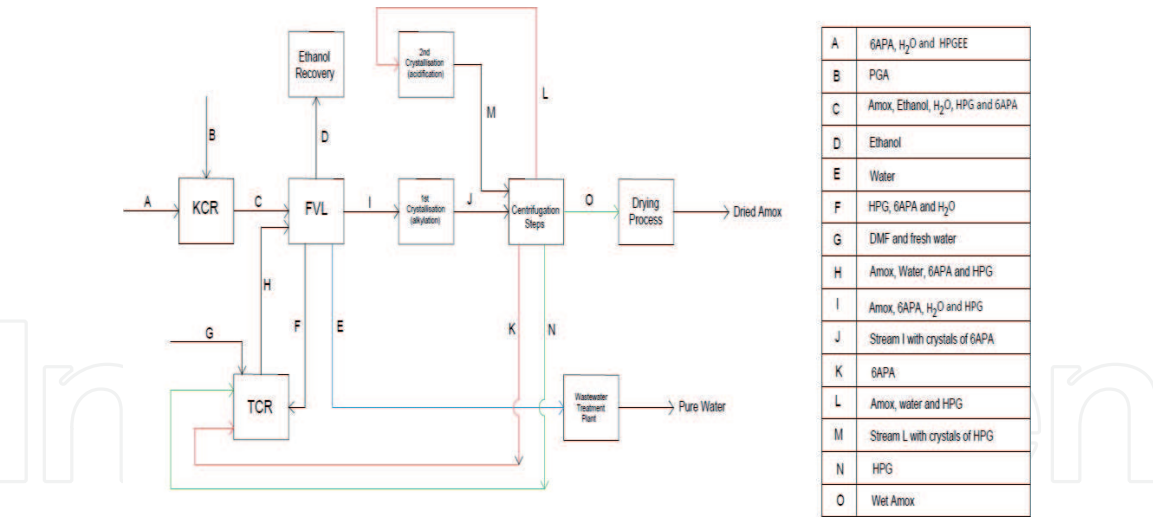


**Figure 8.**  
*GSK manufacturing Plant at Irvine (GSK Website).*

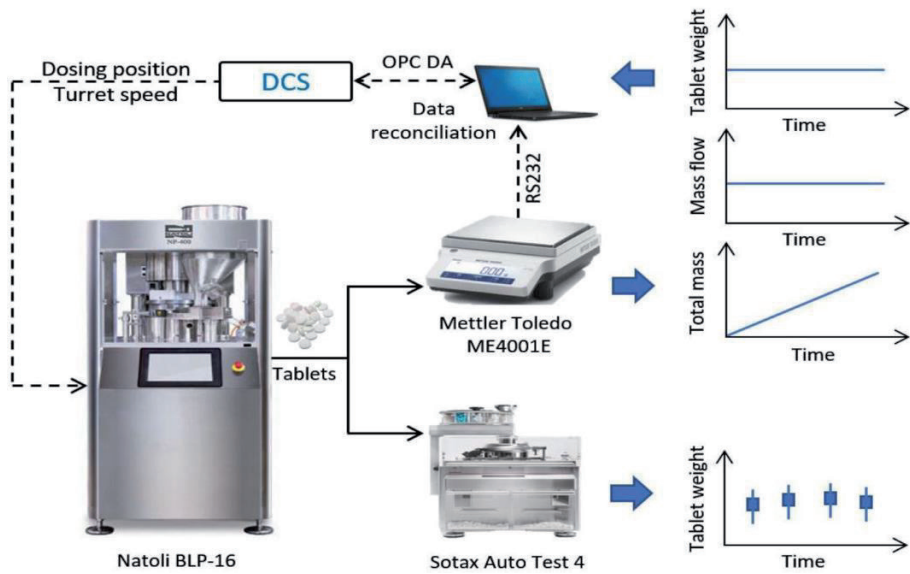
### 3.1 Quality control of the tableting/encapsulating process

The dried amoxicillin produced according to **Figure 9** will now be mass produced into tablets and capsules using automated tableting (**Figure 10**). Tablets are normally manufactured by direct compression or by granulation depending on material properties and the relevant requirements for formulation. During tablet manufacture the powder is fed to the machine and blended before tableting unit





**Figure 9.**  
Process flow diagram for the manufacture of amoxicillin [20].



**Figure 10.**  
Tablet weight measurement real-time monitoring and control [17].

operations kick off. The mass production process would also need to be monitored for consistency by strict quality control procedures.

The tablet press is a multi-stage process split up into stations with each station going through the routine of die filling, metering, pre-compression, main-compression, tablet ejection and take-off from lower punch, as shown in **Figure 10**. After the blend is fed into the die, the metering stage is adjusted to achieve the dosing position, i.e. the volume of powder inside the die. The powder is then locked between upper and lower punches during pre-compression and main-compression until the tablet ejection and take-off stages are reached. The pre-compression stage serves to remove air trapped in the die and to rearrange the particle packing, while the main compression stage compacts and transforms the powder bed into a tablet. The tablet weight can be controlled by changing the dosing position subject to variations in powder bulk density, and in filling time due to changes in turret speed, or in filling efficacy due to changes in powder flow properties. The in-die tablet thickness is determined by the punch displacement which is manually set before the tableting operation for the tablet press used in this study. Hence, the maximum

main-compression force depends on the amount of powder in the die or, equivalently, on the tablet weight.

3.2 Risk assessment of quality assurance and control during mass production of chemicals

Table 2 shows potential risk variables associated with quality control during mass production. It ranges from issues associated with acceptance sampling of materials and products at the input/output stage to contamination from tableting machines, impure product and variation in tablet weight.

Tian et al. [21] carried out quality risk assessment and mitigation of pharmaceutical continuous manufacturing of a case study using flowsheet modelling approach (an engineering approach that can provide a framework to understand the impact of process dynamics on drug quality and associated risks during production, thereby facilitating the development of robust continuous processes) and identified a potential area for model improvement. Using sensitivity analyses they identified the significance of process parameters and material attributes on the dynamic responses and quality attributes of the tablet. They also conducted risk analysis using residence time distribution models to identify the impact of flowrate disturbances on product quality. Consequently, they were able to develop risk mitigation strategies to enable continuous production of high quality tablet.

Risk variables	Impact from risk negligence
(1) Use of acceptance sampling to evaluate input and output materials	(1) (a) Producer's risk (b) Consumer's risk
(2) Inadequate cleaning of manufacturing equipment	(2) Contamination of product with impurities
(3) Chemicals used to decontaminate equipment can react with materials	(3) Contamination of product with impurities
(4) Change in powder bulk density during compaction	(4) Variation in tablet weight
(5) Impurities in reactant chemicals	(5) Impure product
(6) Inaccuracy in the dosing position of the tablet press	(6) Variation in tablet weight
(7) Change in filling efficacy due to changes in powder flow properties	(7) Variation in tablet weight

Table 2.  
Risk assessment of quality control during mass production.

4. Conclusion

This chapter discussed quality control of mass production process in the chemical industry. It reviewed a typical mass production process, identified current practice in the industry in order to guarantee quality assurance during mass production and finally proposed how this could be implemented in the chemical industry. A combination of acceptance sampling and process analytical techniques were deemed suitable for quality control during both batch and mass production.

Quality control during bulk pharmaceutical production was studied where robots and machines were subjected to decontamination quality control procedure. Tableting and encapsulating machines for drug production also needed to be properly calibrated and cleaned to ensure constant tablet weight, and also minimise contamination of products.

Risk assessment of quality control procedures was proposed in order to engender quality assurance during mass production.

## Dedication

This book chapter is dedicated to my son Kelechi Peter Oduoza who died suddenly during the preparation of this manuscript. May his soul and those of all the faithful departed through the mercy of God rest in perfect peace, Amen.

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